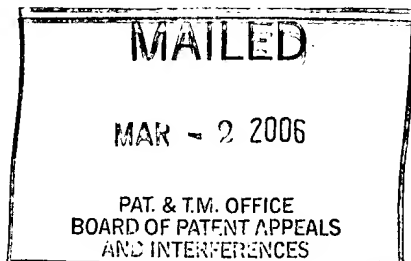




UNITED STATES PATENT AND TRADEMARK OFFICE

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES
BOX INTERFERENCE, WASHINGTON, D.C. 20231

Filed by: Fred E. McKelvey
Telephone: (571) 272-9797
Facsimile: (571) 273-0042



Applicants: Branstrom et al.
Application No.: 09/512,810
Filed: 02/25/00
For: Bacterial delivery system

The above-identified application or patent has been forwarded to the Board of Patent Appeals and Interferences because it is adjudged to interfere with another application or patent. An interference has been declared. The interference is designated as No. 105,428.

Notice is hereby given the parties of the requirement of the law for filing in the Patent and Trademark Office a copy of any agreement "in connection with or in contemplation of the termination of the interference." 35 U.S.C. § 135(c).

Fred E. McKelvey
Senior Administrative Patent Judge

1 The opinion in support of the decision being
2 entered today is not binding precedent of the board.

Paper 1

3
4
5 Filed by:

6 Fred E. McKelvey
7 Senior Administrative Patent Judge
8 Mail Stop Interference
9 P.O. Box 1450
10 Alexandria Va 22313-1450
11 Tel: 571-272-9797
12 Fax: 571-273-0042

Filed 2 March 2006

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15 UNITED STATES PATENT AND TRADEMARK OFFICE

16
17
18 BEFORE THE BOARD OF PATENT APPEALS
19 AND INTERFERENCES
20 (Senior Administrative Patent Judge McKelvey)

21
22
23 ARTHUR A. **BRANSTROM**, DONATA R. SIZEMORE
24 and JERALD C. SADOFF,

25 Junior Party
26 (Application 09/512,810),

27 v.

28
29 ROBERT J. **POWELL**, GEORGE K. LEWIS
30 and DAVID M. HONE,

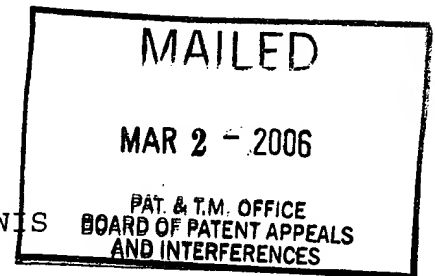
31 Senior Party
32 (Patent 5,877,159).

33
34
35 Patent Interference 105,428 (McK)
36 Technology Center 1600

37
38
39
40
41
42 **DECLARATION**
43 **37 CFR § 41.203(b)**

44
45 **Part A.**
46 **Declaration of interference**

47 1. An interference is declared between the
48 above-identified parties. 35 U.S.C. § 135(a); 37 CFR
49 § 41.203(b).



1 2. Details of the application, patent, counts and
2 claims designated as corresponding or as not corresponding to the
3 counts appear in Parts E and F of this DECLARATION.

4 **Part B.**
5 **Judge managing the interference**
6

7 Senior Administrative Patent Judge McKelvey has been
8 designated to manage the interference. 37 CFR § 41.104(a).

9 **Part C.**
10 **Standing order**
11

12 1. A Trial Division STANDING ORDER (3 Jan. 2006)
13 (Paper 2) accompanies this DECLARATION.

14 2. The STANDING ORDER applies to this interference,
15 including the provisions related to Electronic Filing. See
16 ¶ 105, pages 17-20.

17 **Part D.**
18 **Initial conference call and motions lists**
19

20 Conference call

21 1. A conference call to discuss the interference is
22 set for:

23 4:00 p.m. (1600 hours Eastern time)
24 on Wednesday, 26 April 2006.

25 2. The board will initiate the call.
26

27 Motions lists

28 3. On or before:
29 noon (1200 hours Eastern time) Friday, 21 April 2006,
30 each party shall file, and on or before:

31 5:00 p.m. (1700 hours Eastern time) Friday, 21 April 2006,

1 each party shall serve, a notice stating the relief the party
2 requests, i.e, a motions list including motions the party seeks
3 authorization to file. 37 CFR § 41.120(a); STANDING ORDER ¶ 204,
4 (Paper 2, page 58).

5 4. The default procedure for filing and serving its
6 motions lists are to be filed before being served.

7 5. By filing before service, one party will not have
8 access to an opponent's motions list prior to filing the party's
9 motions list.

10 6. Nevertheless, the parties may mutually agree to
11 discuss and serve motions lists at any time prior to the date and
12 time motions lists are due.

13 7. The following shall be included in any motions
14 list:

15 (1) Proposed motion for benefit must identify the
16 application(s) for which benefit will be
17 sought.

18 (2) Proposed motion to attack benefit must
19 identify the application(s) being attacked.

20 (3) Proposed motion seeking judgment against an
21 opponent based on alleged unpatentability
22 must identify the statutory basis for the
23 alleged unpatentability and:

24 (a) if based on the prior art, identify the
25 prior art;

26 (b) if based on the first paragraph of
27 35 U.S.C. § 112, identify whether

1 written description, enablement and/or
2 best mode will be the basis of the
3 proposed motion;

4 (c) if based on no interference-in-fact,
5 briefly identify the reason;

6 (d) if based on an alleged failure to comply
7 with 35 U.S.C. § 135(b), briefly
8 identify the reason;

9 (e) if claim correspondence is involved,
10 identify any claim to be designated as
11 corresponding or not corresponding to
12 the count;

13 (f) if a new count is to be sought, identify
14 the new count.

15
16 8. A motions list shall not contain any "reservation
17 clause" whereby a party attempts to reserve a right to file
18 additional motions. Additional motions are those authorized by
19 the board consistent with the rules.

20 9. A sample schedule for taking action during the
21 motion phase appears as Form 2 (page 69) in the STANDING ORDER.

22 10. Counsel are encouraged to discuss the schedule
23 prior to the conference call and to agree, essentially consistent
24 with the sample schedule, on dates for taking action.

25 11. A typical motion period lasts approximately eight
26 (8) months.

27 12. Counsel should be prepared to justify any request
28 for a shorter or longer period.

Senior Party³

Named inventors: Robert J. Powell, Maryland
George K. Lewis, Maryland
David M. Hone, Maryland

Patent:⁴ U.S. Patent 5,877,159
issued 2 March 1999
based on application 08/443,790
filed 3 May 1995

Title: Method for introducing and expressing
genes in animal cells and live invasive
bacterial vectors for use in the same

Assignee: University of Maryland at Baltimore

³ The senior party is the party with the earliest accorded priority date as set out in this DECLARATION. 37 CFR § 41.201 (definition of "Senior party"); 37 CFR § 41.207(a) (1).

⁴ The file is a paper file, not an Image File Wrapper (IFW) file. The first maintenance fee was paid on 25 July 2002. See the enclosed RAM Fee History for the patent. The second maintenance fee is not yet due.

Assignment of exhibit numbers
37 CFR § 41.154(c)(1)

1. The senior party [Powell] is assigned exhibit
numbers:

1001-1999

2. The junior party [Branstrom] is assigned exhibit
numbers:

2001-2999

3. If necessary, the board will use exhibit numbers:

3001-3999

Initiating settlement discussions
STANDING ORDER ¶ 126.1 (Paper 2, pages 40-41)

4. The senior party is responsible for initiating
settlement discussions.

1 Part F.
2 Counts and claims of the parties

3
4 Count 1

5 A method for introducing and expressing a nucleic acid
6 in animal cells in vitro comprising infecting said animal
7 cells with live attenuated invasive bacteria selected from
8 the group consisting of Shigella spp, Listeria spp and
9 enterioinvasive Escherichia coli,

10 [1] wherein said bacteria includes a eukaryotic
11 expression cassette containing said nucleic acid,

12 [2] wherein said nucleic acid encodes an antigen, and

13 [3] wherein said antigen is expressed at detectable
14 levels.

15
16 Count 1 is similar to and modeled after Branstrom claim 45
17 and Powell claim 1. The following shows what was deleted from
18 and added to the claims, with the matter in strikeout deleted and
19 the matter in brackets added.

20
21 A method for introducing and expressing a ~~gene~~ [nucleic
22 acid] in animal cells [in vitro] comprising infecting said
23 animal cells with live [attenuated] invasive bacteria
24 [selected from the group consisting of Shigella spp,
25 Listeria spp and enterioinvasive Escherichia coli],

26 [1] wherein said bacteria ~~contain~~ [includes] a
27 eukaryotic expression cassette ~~encoding~~ [containing⁵] said
28 ~~gene~~ [nucleic acid],

29 [2] wherein said ~~gene~~ [nucleic acid] encodes a ~~vaccine~~
30 [an] antigen⁶, [and]

31 ⁵ The cassette contains the nucleic acid; it does not encode it.

32 ⁶ The phrase "vaccine antigen" seems somewhat peculiar; the vaccine the
33 the composition administered and the object of administering the composition
34 is to produce an antigen.

1 [3] wherein said vaccine antigen is expressed at
2 detectable levels, ~~and~~
3 ~~[4] wherein said animals cells are cultured in vitro.~~

Count 2

A method for introducing an immune response in an animal comprising infecting said animal with attenuated live invasive bacteria selected from the group consisting of Shigella spp, Listeria spp and enterioinvasive Escherichia coli,

[1] wherein said bacteria includes a eukaryotic expression cassette containing a nucleic acid,

[2] wherein said nucleic acid encodes an antigen,

[3] wherein said antigen is expressed at levels sufficient to induce an immune response, and

[4] wherein said invasive bacteria are administered to a mucosal surface of said animal.

Count 2 is similar to and modeled after Branstrom claim 53 and Powell claim 15. The following shows what was deleted from and added to the claims, with the matter in strikeout deleted and the matter in brackets added. In addition, it is noted that neither Branstrom claim 53 nor Powell claim 15 contains an antecedent for "said gene" in the phrase "encoding said gene" in the language in each claim which corresponds to that of paragraph [1], supra.

A method for introducing an immune response in an animal comprising infecting said animal with attenuated live invasive bacteria [selected from the group consisting of Shigella spp, Listeria spp and enterioinvasive Escherichia coli],

[1] wherein said bacteria ~~contain~~ [includes] a eukaryotic expression cassette ~~encoding said gene~~ [containing a nucleic acid],

[2] wherein said ~~gene~~ [nucleic acid] encodes a ~~vaccine~~
an antigen,

[3] wherein said ~~vaccine~~ antigen is expressed at levels sufficient to induce an immune response, [and]

[4] wherein said invasive bacteria are administered to a mucosal surface of said animal.

1 The claims of the parties are:

2 Branstrom: 34-35, 37, 39 and 45-59

3 Powell: 1-24

4 The claims of the parties which correspond to Count 1 are:

5 Branstrom: 45-52

6 Powell: 1-6, 9-14 and 16

7 The claims of the parties which do not correspond to Count 1
8 are:⁷

9 Branstrom: 34-35, 37, 39 and 53-59

10 Powell: 7-8, 15 and 17-24

11 The parties are accorded the following priority benefit for
12 Count 1:

13 Branstrom: None⁸

14 Powell: None

16 ⁷ A claim which does not correspond to any count is not involved in
17 the interference within the meaning of 35 U.S.C. § 135(a).

18 ⁸ Branstrom claims benefit of

- 19
20 (1) application 08/711,961, filed 06 September 1996 (an IFW file),
21 (2) provisional application 60/018,035, filed 21 May 1996 (a paper
22 file);
23 (3) application 08,523,855, filed 06 September 1995, now U.S. Patent
24 5,824,538, issued 20 October 1998 (a paper file) and
25 (4) provisional application 60/00,3,318, filed 06 September 1995 (a
26 paper file).
27

28 At this time, it has not been necessary to determine whether benefit should
29 be accorded as to Count 1 because Branstrom has been placed under an order
30 to show cause why judgment should not be entered against it under 37 CFR
31 § 41.202(d)(2). In the event Branstrom overcomes the order to show cause
32 and wants to be accorded benefit of one or more of the above-identified
33 applications, Branstrom may list a motion for benefit in its lists of motions.

1 The claims of the parties which correspond to Count 2 are:

2 Branstrom: 53-59

3 Powell: 15 and 17-23

4 The claims of the parties which do not correspond to Count 2
5 are:⁹

6 Branstrom: 34-35, 37, 39 and 45-52

7 Powell: 1-14, 16 and 24

8 The parties are accorded the following priority benefit for
9 Count 1:

10 Branstrom: None¹⁰

11 Powell: None

13 ⁹ A claim which does not correspond to any count is not involved in
14 the interference within the meaning of 35 U.S.C. § 135(a).

15 ¹⁰ Branstrom claims benefit of

- 16
17 (1) application 08/711,961, filed 06 September 1996 (an IFW file),
18 (2) provisional application 60/018,035, filed 21 May 1996 (a paper
19 file);
20 (3) application 08,523,855, filed 06 September 1995, now U.S. Patent
21 5,824,538, issued 20 October 1998 (a paper file) and
22 (4) provisional application 60/00,3,318, filed 06 September 1995 (a
23 paper file).
24

25 At this time, it has not been necessary to determine whether benefit should
26 be accorded at to Count 2 because Branstrom has been placed under an order
27 to show cause why judgment should not be entered against it under 37 CFR
28 § 41.202(d)(2). In the event Branstrom overcomes the order to show cause
29 and wants to be accorded benefit of one or more of the above-identified
30 applications, Branstrom may list a motion for benefit in its lists of motions.

1 Part G.
2 Heading to be used on papers
3

4 The following heading must be used on all papers filed in
5 this interference. STANDING ORDER ¶ 106.1.1 (Paper 2, page 20).
6

7 UNITED STATES PATENT AND TRADEMARK OFFICE
8
9 _____

10 BEFORE THE BOARD OF PATENT APPEALS
11 AND INTERFERENCES
12 (Senior Administrative Patent Judge McKelvey)
13
14 _____

15 ARTHUR A. **BRANSTROM**, DONATA R. SIZEMORE
16 and JERALD C. SADOFF,
17

18 Junior Party
19 (Application 09/512,810),
20
21

22 v.
23

24 ROBERT J. **POWELL**, GEORGE K. LEWIS
25 and DAVID M. HONE,
26

27 Senior Party
28 (Patent 5,877,159).
29
30 _____

31 Patent Interference 105,428 (McK)
32 Technology Center 1600
33 _____

Part H.
Order form for requesting file copies

1. When requesting copies of files, a party shall use STANDING ORDER Form 4 (page 71).

2. Use of Form 4 will expedite processing of any request.

3. A party should attach to any request for file copies a photocopy of Part E of this DECLARATION with a hand-drawn circle around the patents and applications for which a copy of a file wrapper is requested.

4. The parties are advised that a single order for files may be filled by the Office of Public Records at more than one time, particularly in a case such as this one involving both paper and IFW files. STANDING ORDER ¶ 109.2 (Paper 2, pages 25-27).

Part I.
Required paragraph for affidavits and declarations

1. The board has experienced cases in which a witness has belatedly advanced reasons why the witness would be unable to appear for cross examination at a reasonable time and place in the United States.

2. Consequently, to prevent surprise and hardship to the party relying on the testimony of the witness, the following paragraph must be included on the signature page of all affidavits (including declarations) filed in this case .

STANDING ORDER ¶ 157.2 (Paper 2, pages 52-53):

In signing this affidavit (declaration), I understand that the affidavit (declaration) will be filed as evidence in a contested case before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. I also acknowledge that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

/s/s/Fred E. McKelvey
FRED E. MCKELVEY,
Senior Administrative Patent Judge¹²

2 March 2006
Entered at: Alexandria, VA

¹² As part of board efforts under the government Paperwork Elimination Act, signatures on papers originating from the board have been phased out in favor of a completely electronic record. Consequently, in this case papers originating at the board will not have signatures. The signature requirements for the parties have not changed. See, e.g., 37 CFR § 10.18 (2005).

1 Enc:

2
3 STANDING ORDER (3 Jan. 2006) (Paper 2)
4 NOTICE OF REQUEST FOR ASSISTANCE ON TECHNOLOGY
5 and ORDER (Paper 3)
6 ORDER TO SHOW CAUSE (Paper 4)
7 NOTICE TO DEPARTMENT OF JUSTICE (Paper 5)
8

9 The following additional documents (1) are provided to
10 permit the parties to gain an early appreciation of the nature of
11 the interference and (2) do not constitute complete copies of any
12 file. They are not part of the record of the interference and
13 cannot be relied upon in the future merely because they are
14 enclosed with this DECLARATION. If a party would like any of the
15 following documents considered in the interference, the party
16 should make the document an exhibit and offer the exhibit in
17 evidence.
18

19 Index of claims in application 09/512,810
20 Claims 34-35, 37, 39, 45 and 47-59 of application 09/512,810
21 Claim 46 of application 09/512,810
22 U.S. Patent 5,824,538
23 U.S. Patent 5,877,159
24 U.S. Patent 6,531,313 B1
25 RAM Fee History for U.S. Patent 5,877,159
26 Bibliographic data
27 Election and traverse filed 13 July 2001
28 Office action entered 14 July 2004
29 Response filed 17 August 2004
30 Document transmitting suggestion for interference from
31 Technology Center 1600 to the board dated 3 May 2005
32 and received by the board on 9 February 2006
33 Explanation, Cahn declaration and Exhibits 1 through 9
34 related to Branstrom Rule 608(b) showing

1 cc (via overnight delivery):

2
3 Attorney for Branstrom
4 (real party in interest
5 United States of America
6 as represented by the
7 Secretary of the Army):

8
9 Office of the Staff Judge Advocate
10 U.S. Army Medical Research and Materiel Command
11 ATTN: MCMR-JA (Ms. Elizabeth Arwine)
12 504 Scott Street
13 Fort Detrick, MD 21702-5012

14
15 Maurice U. Cahn, Esq.
16 Cahn & Samuels, LLP
17 2000 P Street, N.W. (Suite 200)
18 Washington, D.C. 20036

19
20 Tel: 202-331-8777
21 Fax: 202-331-383
22 Email: None

23
24 Attorney for Powell
25 (real party in interest
26 University of Maryland):

27
28 SUGHRUE MION ZINN MACPEAK & SEAS
29 2100 Pennsylvania Avenue, N.W.
30 Washington, D.C. 20037-3202

31
32 Tel: 202-293-7060
33 Fax: None
34 Email: None

35
36 Attorney for the United States [28 CFR § 0.45(f)]:

37
38 Hon. John Fargo, Acting Director
39 Commercial Litigation
40 Civil Division
41 U.S. Department of Justice
42 Washington, D.C. 20530

43
44 Office physical location:
45 1100 L Street, N.W.
46 Room 11116
47 Washington, D.C. 20530

48
49 Tel: 202-514-7223
50 Fax: 202-307-0345